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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,054	07/23/2001	Mayumi Tomikawa	522.1921D	4839

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EXAMINER

MORAN, MARJORIE A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,054

Applicant(s)

TOMIKAWA ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-11, 21 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-11, 21, 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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All objections and rejections not reiterated below are hereby withdrawn.

Claims 5-11, 21, and 24 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 11/3/04 has been entered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5-11 and 24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The amended claims are directed to a computer-implemented process. Amended claim 1 recites a step of displaying data, but does not limit this step to be one which is performed outside the computer; i.e. a physical step or action. A step of merely displaying the results of a computer-implemented process, wherein neither the process itself nor the result is statutory, does not render the process statutory. No physical acts or other "safe harbors" are recited in the claims; however, as set

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forth in the previous office action, a computer-implemented method comprising only steps of data manipulation MAY be statutory when the result produced is concrete, tangible and useful. The method of claims 5-11 and 24 does not produce a concrete, tangible and useful result, as previously set forth and further elucidated below.

As set forth in MPEP 2106.IV.B:

“In practical terms, claims define nonstatutory processes if they:

– consist solely of mathematical operations without some claimed practical application

(i.e., executing a “mathematical algorithm”); or

– simply manipulate abstract ideas, e.g., a bid (Schrader, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application.”

And at MPEP 2106.IV.B.2(b) (ii):

“A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of

producing something that is concrete, tangible and useful. See AT &T, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in State Street, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being claimed (as in

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Alappat, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc). For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory.

The “practical application” toward which the claims are apparently directed is the analysis of a three dimensional structure. The claims recite steps of calculation and display of 3D structures corresponding to two sets of points, wherein the point sets are limited to be sequence listings and at least one structure is a protein. There is no recited step of determining or indicating a degree of similarity between the structures, or of calculating similarity of the protein to a known structure. The result of the mathematical calculation, per se, is not a concrete, tangible, and useful result as one skilled in the art would not know what the result is intended to indicate.

Applicant's arguments filed 11/3/04 have been fully considered but they are not persuasive. In response to the apparent argument that limiting one of the structures to a protein and the points to sequences renders the claims statutory, it is noted, as set forth above, that merely displaying the result of a calculation, even when the structure is limited to a protein, does not render claims statutory. What is “concrete, tangible, and useful” about a “picture” (i.e. graphic display in 3D) of amino acid sequences or one or more protein structures, per se, with an unknown degree of similarity? For example, one may display graphic or 3D representations of two sequences or proteins in a textbook. This is appreciated by a student studying biochemistry or crystallography, but does not render the

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graphic, the book, nor the act of either printing or viewing the graphic statutory subject matter under 35 USC 101. For these reasons, and those previously set forth, the examiner maintains that the claims do not recite statutory subject matter, and maintains the rejection.

Claims 5-11, 21, and 24 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Applicant has not set forth any arguments specific to this rejection.

The claims recite a method for analyzing three dimensional structures, and an apparatus for performing the method. The claimed method steps result in calculation of a root mean square distance between elements belonging to two sequences. These sequences are not limited to be from two different structures, While "at least one" structure is limited to be a protein, it is noted that the sequence listings may represent different sections of the same protein. Further, the sequence listing are not limited to be amino acids, therefore they may represent comparison of different "domains" of any structure; e.g. a nucleic acid. The claims therefore still encompass comparison of point sets from different areas of domains of the same compound or molecule. The specification does not disclose a utility for comparing different parts of the same compound or molecule and none is apparent. The claim also encompass point sets from two different structures, whereupon the method may presumably be used to compare different compounds or molecules, specifically proteins. A "use" of the inventive method for comparing different compounds (e.g. enzymes) is set forth and

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exemplified in the specification on pages 46-52. However, while the example of the specification provides results of the comparison, there is no disclosure for what one skilled in the art would, in fact, use this information *for*. The specification also asserts, on page 5, that the inventive method may be used to extract motifs. However, an extraction of motifs requires a determination of a degree of similarity between two proteins/sequences/structures. The claims do not recite any step or limitation for determining a degree of similarity. Merely elucidating how far apart elements of compounds are is not an indication that the compounds are, in fact, similar enough to identify the elements as comprising (presumably conserved) motifs, or are different, such that the elements can be eliminated from further consideration/comparison. The claims do not identify any particular compounds for comparison. Even where the claims encompass proteins, in the absence of any knowledge of identity, function, etc. of the proteins being compared, nor any determination of a degree of similarity between two proteins, the claims do not provide an "immediately useful" result. According to MPEP 2107.01 and as set forth in *Brenner v. Manson* (148 USPQ 689 (1966)) and *In re Ziegler* (26 USPQ2d 1600), a "useful invention" is one wherein the "usefulness" is "immediately apparent to those familiar with the technological field of the invention. As further set forth in MPEP 2107.01, a "use" to do further research, or assaying for or identifying a compound which itself has no, or an unknown utility, is not considered a "substantial utility" under 35 USC 101. As the structures being "assayed" are unknown/not identified in the claim, their utility is unknown. More information and/or further research would be required by one

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skilled in the art to know what to do/how to use the results of the claimed method and apparatus, as set forth above. For these reasons, the examiner maintains that the claims lack utility, and maintains the rejection.

Claims 5-11, 21, and 24 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-11, 21 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Generating an optimum combination in view of "at least one" of a geometric relationship, a threshold value, and refining elements is new matter.

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The original claims did not recite limitations with regard to optimum combination. The specification, on page 30, lines 14-17 and page 32, lines 18-22, provides support for generation of an optimum combination "in view of" a geometric relationship, a threshold value condition, AND an attribute of points. Nowhere does the originally filed specification teach generating an optimum combination based on only one, or only two of the listed "conditions," as is embodied in the "at least one" language of the new limitation to claims 5 and 21. As neither the original claims or specification provide support for the newly recited limitations, the claims recite new matter.

Claims 5-11, 21, and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

A method or apparatus comprising a step or means for generating a combination of correspondence satisfying a condition, as recited in claims 5 and 21, is not enabled as neither the specification nor prior art provide guidance for

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how to determine if a combination of correspondence "satisfies" a condition. The instant specification discloses/exemplifies on pages 27 et seq. various methods of analyzing three dimensional structures. The specification admits on page 29 that merely comparing two data sets (i.e. merely generating a "combination of correspondence" between two data sets) renders it "nearly impossible" to effect a calculation (of rmsd?) since so many combinations are possible. The disclosure of the specification, therefore, indicates that some sort of "condition" must be met in order to enable the inventive method. Page 30 then discloses that an "optimum combination" must be generated "in view of" a geometric relationship within the data sets, a threshold value condition, and an attribute of points. Following pages exemplify "ordering" points, refining candidates based on a distance relationship, on angle relationships, or on distances and angles from a center of gravity, and using a threshold value condition. Nowhere does the specification teach how to determine if these "conditions" are met or "satisfied" by a combination of correspondence (i.e. comparison of data). Rather, it appears that the "conditions" of the specification are used to compare data sets, or *create* combinations of correspondence. There is no disclosure for how to determine what requirements must be met in order to determine if a particular combination (comparison) "satisfies" the condition.

Figures 15 and 17 comprise flow charts which appear to correspond, at least in part, with the claimed method and apparatus. These Figures contain an box asking if a previous step "satisfies a restriction condition?" but neither Figure sets forth any step or means for determining what conditions are required in

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order to determine a "yes" or "no" answer. Figures 36 and 37 comprise flow charts which appear to reflect generating a correspondence of data based on conditions similar to those disclosed in the specification, and disclose particular equations for selecting data from a single data set BEFORE determining a correspondence with a second data set. The claims specifically recite generating a combination of correspondence satisfying a condition BETWEEN elements of a first set and elements of a second set (of data), therefore Figures 36 and 37 do not appear to be a teaching for how to perform the claimed method or how to use the claimed apparatus.

The prior art of PANTOLIONO (IDS ref: US patent 4,853,871) teaches a method for analyzing and comparing three dimensional structures using 3D coordinates and calculation of root mean squares to determine fit; i.e. distance (col. 8, lines 32-65), but does not teach that any "conditions" must be met or satisfied in order to generate the comparison and/or perform the root mean square calculation.

The level of skill in the art is considered to be high. However, given the lack of guidance in either the specification or the prior art for how to determine whether a combination of correspondence between two point sets meets or satisfies a condition, and as one skilled in the art would be required to guess at the parameters necessary to perform such a determination or calculation, it would require undue experimentation by one skilled in the art to generate a combination of correspondence satisfying a condition. For these reasons, the claims are not enabled.

Respons to Arguments

Applicant's arguments filed 11/3/04 have been fully considered but they are not persuasive. In response to the argument that the amended claims now identify conditions to be satisfied, it is noted that the neither the specification nor the claims teach or recite HOW to satisfy the identified conditions. Mere knowledge of what a condition IS does not enable to one skilled in the art to determine when that "condition" has been met or satisfied. For example, claim 5 now limits a condition to comprise "generating an optimum combination in view of" a geometric relationship. How does one skilled in the art determine when an "optimum" combination has been generated? Has the condition been "satisfied" when the "optimum combination" has been generated, or is the generation a step of *creating* the condition, which then must be satisfied by the earlier recited "generation of a combination of correspondence"? Are both steps of generation and combination the same? If so, then how does one simultaneously generate AND satisfy a condition? (See also the rejection under 35 USC 12, 2nd paragraph.) Claim 5 also limits a condition to include a threshold value condition, but again, does not recite how to satisfy that condition. One skilled in the art would not know if the threshold must be met, exceeded, or NOT exceeded. Claim 5 further limit a condition to be "refining" elements. One skilled in the art would not know how refined the elements must be in order for this condition to be "satisfied." Nor would one skilled in the art know how to use the attributes to

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"refine" the elements such that a condition could be met. The specification is silent with regard to these issues.

Applicant further argues that the specification provides a written description of the conditions to be satisfied. It is noted that the rejection made is for lack of enablement, not lack of written description. While the specification does provide at least partial support for the recited conditions, as set forth above, the examiner maintains that it does not provide an *enabling* disclosure for how to generate a combination of correspondence to satisfy those conditions. For these reasons, and those set forth above, the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 21 recite generating a combination of correspondence "satisfying" a condition. As set forth above, the specification does not disclose what requirements must be met in order for a combination of correspondence to "satisfy" a condition. The claims do not recite any such requirements. As the metes and bounds intended by applicant with regard to "satisfaction" of a condition are not defined by the specification or in the claims, applicant's intended limitations are unclear and the claims are indefinite.

The term "optimum" in claims 5 and 21 is a relative term which renders the claim indefinite. The term "optimum" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the

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invention. As one skilled in the art would not know the metes and bounds intended by applicant for an "optimum combination", the claims are indefinite.

Claims 5 and 21 recite generating an optimum combination "in view of" a geometric relationship between point sets. It is unclear what method steps or calculations are intended by the phrase "in view of", therefore the claims are indefinite.

Claims 5 and 21 recite a step (a) of generating a combination of correspondence between elements of two point sets, wherein the combination of correspondence must satisfy a condition. The claims then limit the condition to comprise generation of a combination "in view of" the same point sets. This appears to be a reiterative step and is nonsensical. It is unclear whether applicant intends both generation steps to be the same? It is further unclear whether applicant intends that a condition be simultaneously generated and satisfied. For these reasons, the claims are indefinite.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722.

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The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
11/29/05